Meeting Notes

Health Information Technology Advisory Committee
March 20, 2019, 08:30 a.m. – 01:00 p.m. ET
In Person

The March 20, 2019, meeting of the Health IT Advisory Committee (HITAC) and Prior Authorization Hearing was opened at 8:30 a.m. ET by **Lauren Richie**, Designated Federal Officer (DFO), Office of the National Coordinator for Health IT (ONC).

Roll Call

MEMBERS IN ATTENDANCE

Carolyn Petersen, Individual, Co-Chair
Robert Wah, Individual, Co-Chair
Michael Adcock, Individual
Christina Caraballo, Audacious Inquiry
Tina Esposito, Advocate Aurora Health
Cynthia A. Fisher, WaterRev, LLC
Brad Gescheider, The Learning Corp
Valerie Grey, New York eHealth Collaborative
Anil Jain, IBM Watson Health
John Kansky, Indiana Health Information Exchange
Kensaku Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Leslie Lenert, Medical University of South Carolina
Arien Malec, Change Healthcare
Denni McColm, Citizens Memorial Healthcare
Aaron Miri, The University of Texas at Austin, Dell Medical School, and UT Health Austin
Brett Oliver, Baptist Health
Raj Ratwani, MedStar Health
Steve L. Ready, Norton Healthcare
Ram Sriram, Federal Representative, National Institute of Standards and Technology (NIST)
Sasha TerMaat, Epic
Lauren Thompson, Federal Representative, DoD/VA Interagency Program Office
Andrew Truscott, Accenture LLP
Sheryl Turney, Anthem BCBS
Denise Webb, Individual

MEMBERS NOT IN ATTENDANCE

Kate Goodrich, Federal Representative, Centers for Medicare and Medicaid Services (CMS)
Clement McDonald, National Library of Medicine
Terrence O'Malley, Massachusetts General Hospital

Chesley Richards, Federal Representative, Centers for Disease Control and Prevention
Patrick Soon-Shiong, NantHealth

ONC STAFF

Elise Sweeney Anthony, Executive Director, Office of Policy
Cassandra Hadley, HITAC Support
Andrew Gettinger, Chief Clinical Officer
Michael Lipinski, Director, Division of Regulatory Affairs
Thomas Mason, Chief Medical Officer
Lauren Richie, Designated Federal Officer
Donald Rucker, National Coordinator

Call to Order

Lauren Richie conducted roll call and called the meeting to order and turned the meeting over to Donald Rucker, National Coordinator.

Welcome Remarks

Donald Rucker shared that ONC has identified a large and important opportunity for the country in interoperability which was teed off by the work done by Andy Gettinger and Tom Mason on the draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*. The prior authorization process is broken. Looking at it more closely, the disconnect may be that financial data is uncoupled from clinical data. This is important as it relates to prior authorization and is similar to the computational payload that is needed for patients to get a price. This is also similar to a payload that is needed for clinical decision support (CDS). During today's discussion, there will be presentations around this. He turned it over to Bill Stead, chair of the National Committee on Vital and Health Statistics (NCVHS).

Bill Stead started by introducing his colleagues.

- Alexandra (Alix) Goss, NCVHS member
- Rich Landen, NCVHS member
- Debra Strickland, NCVHS member
- Rebecca Hines, DFO
- Loraine Doo, lead staff to the standards committee

Bill Stead asked how there might be alignment between administrative and clinical standards so that the clinician's information system may submit prior authorization requirements to payers and then the payers may adjudicate in a way that does not require manual effort. He questioned how to better tie clinical and financial data.

Robert Wah shared that the committee is excited about the discussion and the opportunity to discuss and learn more about prior authorization. This is a major topic for physicians and patients.

Patient/Clinician Perspective Panel

Andrew Robie Md, Family Medicine Physician, Anacostia Community Health Center, Unity Health Care

Andrew Robie commented that for many, the worst part of the job is prior authorization due to the time and resources it consumes. The other concern is the delay it causes patients to receive their care and/or medication.

- There is a lot of important work that this takes away from (e.g., patient education, patient follow-up)
- His presentation focused on medication prior authorization because that is what most closely relates to his work.
- To detail the problems with prior authorization, he provided a scenario based on a fictitious patient, Mr. Jefferson who has uncontrolled diabetes. He detailed the many pains encountered throughout the process, using the example below:
  - Mr. Jefferson is to start insulin to control blood sugar. In an ideal circumstance, the drug formulary is in the EHR and is approved by the payer.
  - There are times when the formulary is unknown which means he has to go to the payer's website to find the formulary information. Doing this search on the website, he hopes tp pick the correct one from so many options. Ideally, this would be much easier to find with better formulary in the EHR or at a minimum on the payer website.
  - He couldn't find the formulary, and it was taking too long, so he just prescribed the drug.
  - When the patient goes to pick up the prescription, the drug is not available.
  - Worst case scenario which is the most common, the pharmacist tells the patient to call the physician's office
    - Just making a call can be tough (busy phone lines, no phone)
    - This requires another call to the pharmacy
  - Paper PA forms, (which could be easily sent from the EHR in another way to the payer is sent via fax. This could be standardized across payers and then use interoperability to share information.
  - Best case, a third-party service notifies the physician to check on the status of the PA. More frequently a fax is sent to the provider. The payer notifies the patient, but the physician doesn't know and often doesn't receive any notification.
  - The form found on the internet was wrong. They were faxed back with a different form that was correct.
  - It took seven days to get the insulin. In that time the patient called the office 4-5 times.
    - In this time, the patient went to the emergency room because he didn't know what to do and was worried about his blood sugar levels.

Andrew Robie concluded that this process could be better and easier. The systems need to be safer to improve patient care.

Heather McComas, PharmD, Director, Administrative Simplification Initiatives, American Medical Association (AMA) (Remote)

Heather McComas shared that the AMA hears concerns about PA frequently.

2018 AMA PA Survey Overview

- 1000 practicing physician respondents
- 40% PCPs/60% specialists
- Web-based survey
- 29 questions
- Fielded in December 2018

Prior Authorization

- It impacts patients. It is a process that takes place before care is delivered.
- Wait at least one business day to hear back from health plans.
- Overwhelming majority (91%) report that it can delay delivery of care.
- Impacts patient health and their clinical outcomes.
- 75% report that PA can lead to treatment abandonment
- PA can have a negative impact on clinical outcomes.
- 28% of physicians report that PA has led to a serious adverse event for a patient in their care (examples were provided)
- From an economic perspective leads to higher costs;working against the goal of PA.
- 88% report PA burdens have increased over the last 5 years
- 31 average total PAs per physician per week – major contributor to administrative burden.

Healthcare is About Patients

- FixPriorAuth.org
    - This website has physician and patient facing facts. Verbiage understandable to both audiences. Over 500 stories about improving care delivery. There is a social media campaign and a petition on the website for PA reform.
- She shared several patient stories, hoping that these stories are kept in mind throughout the discussion.
- The PA process is broken. An important landmark was the releases of the Prior Authorization and Utilization Management Reform Principles from AMA and 16 other organizations.
    - Five "buckets" addressed:
        1. Selective application of PA
        2. PA program review and volume adjustment
        3. Transparency and communication regarding PA
        4. Continuity of patient care
        5. Automation to improve transparency and efficiency

Heather McComas concluded that progress is slow. PA interferes with patient continuity of care, treatment is disrupted, and patients can be harmed.

Interoperability and HIPAA Administrative Simplification Considerations

Daniel Kalwa, Policy Advisor, Division of National Standards, Centers for Medicare and Medicaid Services (CMS)

Division of National Standards

- Clarify policy related to the transaction standards and operating rules required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Affordable Care Act (ACA);
- Educate and provide technical assistance about the adopted standards and operating rules to support the affected stakeholders, using collaboration and outreach;
- Enforce HIPAA policies through complaint investigations, corrective action plans, and compliance reviews.

National Committee on Vital Health Statistics

"The NCVHS serves as the statutory [42 U.S.C. 242k(k)] public advisory body to the Secretary of Health and Human Services (HHS) for health data, statistics, privacy, and national health information policy and the Health Insurance Portability and Accountability Act (HIPAA). The Committee advises the HHS Secretary, reports regularly to Congress on HIPAA implementation, and serves as a forum for interaction between HHS and interested private sector groups on a range of health data issues." 42 U.S. Code § 1320d–1(f) requires that the Secretary "shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section [242k(k) of this title] and shall consult with appropriate Federal and State agencies and private organizations."

Standards for Information Transactions

42 U.S. Code § 1320d–2(a)(2) lists the transactions for which the Secretary must adopt standards: (A) Health claims or equivalent encounter information. (B) Health claims attachments. (C) Enrollment and disenrollment in a health plan. (D) Eligibility for a health plan. (E) Health care payment and remittance advice. (F) Health plan premium payments. (G) First report of injury. (H) Health claim status. (I) Referral certification and authorization. (J) Electronic funds transfers. NCVHS is responsible for making recommendations on standards HHS considers adopting for the above transactions. The DNS, which has been delegated the authority to administer HIPAA Administrative Simplification, considers NCVHS recommendations in adopting standards.

Steps of Prior Authorization in Health Care

The Health Care Prior Authorization process includes many steps. The broadest process would include the following steps:

1. The Healthcare Provider checks patient's eligibility to receive a health care service with the patient's Health Plan.
2. The Health Care Provider checks that a proposed service is covered by the Health Plan.
3. The Health Care Provider checks the Health Plan's prior authorization requirements for the proposed service.
4. After collecting the information the health plan requires for a prior authorization, the Health Care Provider submits that information to the Health Plan.
5. The Health Plan replies to the Provider's request.

HIPAA Administrative Simplification Impact on Prior Authorization

HIPAA Administrative Simplification has a direct impact on conducting prior authorizations in three of the steps described above:

- Step One is adopted in 45 CFR Subpart L - Eligibility for a Health Plan.

- Steps Four and Five:
  - The Prior Authorization transaction is adopted in 45 CFR Subpart M - Referral Certification and Authorization.
  - The Health Claims Attachment standard and operating rules have not been adopted.

Requirement for Operating Rule

Operating rules, which are required by the ACA, are defined as "the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications." Operating rules set certain requirements for transactions that are covered by HIPAA. They specify, for example, the information that must be included when conducting standard transactions, making it easier for providers to use electronic means to handle administrative transactions. They are intended to offer additional guidance on how to implement and utilize adopted standards. In the context of adopted HIPAA standards, they often include requirements around transport, security, and processing time.

Considerations for Future Prior Authorization Standards

Both HITAC and NCVHS are considering standards related to Prior Authorization for recommendations. We suggest that each committee consider the following as it formulates recommendations:

- Do standards proposed for a particular step in the Prior Authorization process align well with standards adopted for other steps? What guidance is necessary to support the implementation of the proposed standard in an environment with existing implementations of prior authorization standards?
- Are the current adopted standards for a step being replaced? Modified? Used in conjunction depending upon business case?
- Where the standards being proposed interact with HIPAA standards, have the interactions with Operating Rules been considered?

Daniel Kalwa thanked the committees for their time and looks forward to recommendations.

Discussion

Arien Malec noted that in his day job he runs research and development for clearinghouse businesses. As Bill Stead noted, there is an approach that assumes administrative and clinical workflows will always be disconnected. Electronic Data Interchange (EDI) standards have proven their worth in large scale transaction volume but are disconnected from the clinical side. It would be helpful to start to think about an API ecosystem and creating a FHIR variance of transaction sets. Innovative start-ups have been tackling consuming EDI. Moving to an API based approach will provide a better system where workflows can plug into. Better ecosystem to take SMART on FHIR or CDS hooks and plug it into eligibility and referral authorization workflows. This is an ecosystem issue, and there is a need to coordinate payers, pharmacy benefit manager (PBMs), providers, and others. Now is a good time to contemplate a different approach to administrative transactions to harmonize administrative and clinical transactions.

Les Lenert commented that "he who has the gold is making the rules." It is time to focus on delivering the maximum value to patients. There is minimal evidence that current PA programs impact of the cost

of care in a positive way. This is just cost shifting. Need to re-engineer and focus on the data sources. Need to identify the most efficient process for the patient. Don't delay a drug to have economic benefits that could potentially hurt the patient.

Carolyn Petersen commented that there is a need for a process that puts the patient at the center.

Arien Malec commented that a number of people have tried to switch from using ICD-10 and Current Procedural Terminology (CPT) that backs adjudication and flip to Systematized Nomenclature of Medicine -- Clinical Terms (SNOMED-CT) to adjudicate claim transactions. John Halamka (Chief Information Officer, Care Group, Inc.) put out a paper in the past arguing for this point. The perspective that is needed with respect to a transition is a perspective that recognizes that the adjudicators for Medicare transactions and commercial payers have built a huge set of assets that do adjudication. The cost to change would be significant. There is a need to understand the U.S. taxpayer cost to that transition. CMS may need to re-write the adjudication systems.

Andrew Truscott noted that he is interested in hearing from Andie Robie regarding the impact on patient outcomes and administrative systems.

- **Andrew Robie** commented that any system that reduces administrative work he is in support of. There is a need to require prior authorization for some patients that he serves, but many are not for items that are clinically relevant or going to improve outcomes. Putting the onus on the payer would be good.

Les Lenert commented that with the advances of deep learning, there is the ability to predict whether an authorization should or shouldn't be provided; and it is not difficult. Need to rethink the process. Need to move forward to modern architecture.

Cynthia Fisher commented that Leslie's idea is substantial. She stated that there are opportunities to move forward and this almost looks like information blocking. She stated that we are in a moment of time when it is necessary for innovation to be used to improve patient care.

Industry Standards Perspective

INDUSTRY ADMINISTRATIVE TRANSACTION DATA

April Todd, Senior Vice President, CAQH Core, CAQH Index Data Report

April Todd shared that the Council for Affordable Quality Healthcare (CAQH) Initiatives simplify healthcare business processes.

- National operating rule author to support interoperability. Currently working on operating rules for:
  - prior authorization
  - attachments/additional clinical information
  - value-based payment
- Rules that went out for industry vote last week
- Ability to track progress within the industry and identify where there are barriers.
- Collaborative effort with multi-stakeholder council.
- Survey is informed by providers, vendors, and healthcare community.
- Transactions are not always easy for providers to report on

Index Definitions

- Transaction Costs - Cost and saving estimates only account for labor time required to conduct the transaction. Systems costs as well as pre-work and follow-up work are not included.
- Electronic Transaction - Automated transaction conducted using a HIPAA standard.
- Manual Transaction - Transaction requiring end-to-end human interaction, such as telephone, fax, and/or mail.
- Partially Electronic Transaction - Includes web portals and interactive voice response (IVR) systems.

NORC Study

- Study conducted to understand how this is working in the provider workflow and better understanding of what is actually happening.
- Despite the continued increase in volume, the potential savings opportunity dropped, suggesting that the industry is becoming more efficient in conducting administrative transactions.
- Increase due to eligibility and benefit transactions. This is a result of the increase in the complexity of the healthcare system.
- Reached a tipping point of electronic adoption.
- There is low electronic adoption within the industry for PA.
- Increase of PA transactions of 12%; however, one of the lowest volume transactions between providers and health plans.
- There is a lack of an attachment standards to support the transformation.
- Some states require manual process
- National standard exists yet electronic adoption trails other transactions with standards.

Multiple reasons for low electronic adoption

- Lack of vendor support – only 12% of systems offer services for electronic prior authorization (2017 Index).
- Lack of federal attachment standard to support transmission of clinical data.
    - State mandates requiring manual processes.
- Vendors that support transactions have higher adoption.

Attachments and Prior Authorization

- Electronic attachments ease workflow related to claims and prior authorizations by providing additional clinical information.
- Electronic adoption level for attachments reported at 6% (2017 Index).
- In 2018/2019 CAQH CORE Attachments Environmental Scan, participating health plans reported
    - 12% exchanged via EDI (primarily pilots)
    - 18% exchanged via web portals
    - 70% of attachments sent via mail and fax
- Most respondents to the 2018/2019 CAQH CORE Attachments Environmental Scan are waiting for a federal attachment standard to transmit clinical information electronically:
    - 44% identified waiting for regulatory direction as the primary reason for delay
    - 23% reported waiting for industry direction as the primary reason for delay
    - 9% listed budget constraints as the primary reason for delay

April Todd concluded that the absence of a federal attachment standard is impacting electronic adoption for the exchange of clinical information and prior authorizations.

MEDICATION WORKFLOW

Anthony Schueth, CEO, Point of Care Partners

Tony Schueth shared that there are different types of prior authorization and his discussion will focus on drugs.

Different Types of Prior Authorization

- Drugs
- Devices
- Procedures

Prior Authorization History

- HIPAA passed in 1996
- Multi-SDO Task Group Formed
- NCVHS held hearings in 2005
- Pilots in 2006
    - Four of five pilots tested PA
- Results from pilots went to a report to Congress and recommended a new standard
- Agency for Healthcare Research and Quality (AHRQ) formed an expert panel and put together a roadmap
    - Decided a pharmacy standard was needed and should be created with NCPDP (chose SCRIPT standard for PA for drugs)
- Minnesota passed a law that was a driver
- In 2011, CVS/Caremark conducted a pilot with several organizations to pilot the new standard
- The industry chose to continue with NCPDP SCRIPT
- Standard published in 2013
- Implementation began in 2015

Tony Schueth noted that PA is part of the prescribing process; at least that is how it is envisioned. Payers aggregate National Council for Prescription Drug Programs (NCPDP), standards (formulary and benefit) and Surescripts aggregates into a file. Surescripts works with EHRs, the night before the patient visits, a query is run on the patient to connect them to the accurate formulary.

- When the provider doesn't see anything, the patient hasn't been identified accurately

Prospective PA

- When the provider knows the patient requires PA
- Hoping for an automated prospective process so that when the patient leaves the practice, he knows what he is going to get at the pharmacy
- If the provider doesn't know PA is required. The pharmacy submits a claim
    - These are rejected 11% of the time
        - Of those, 66% are due to PA
        - The remaining 33% just give up on the process

- This kicks off retrospective PA

Retrospective PA

- When the claim is rejected
- Pharmacy sends the PA to the physician through a different channel
- Now outside the workflow
- It is a catch that is electronic, but it is a retrospective process

Tony Schueth commented that this process is suboptimal. When it is a prospective process, patients get therapy 13.2 days faster. In today's environment, 65% are retrospective, 35% are prospective.

He noted that when the process was designed in 2006, physicians didn't have high-speed internet. Real-time request response wouldn't have worked at that point in history. The information included in the formulary standard works well. The problem is because the information is at a plan level, or best case the group level, not the individual patient level.

- The information can look like it is wrong because it isn't on the right level
- Commercial plans don't often have the formulary PA flag; it is only available 33% of the time
- On the Medicaid side it is included

Solutions to the Formulary Problem

- Real-time pharmacy benefit check (RTPBC) is a solution.
  - Real-time transaction being implemented in the industry by innovators and early adopters.
  - This is designed to provide the patient level information at the point of care.
  - Includes the patient out of pocket costs for transparency.
  - Provide alternatives if not approved.
  - Identifies where the pharmacy could be.
  - NCPDP standard, will be more tightly integrated into EHRs

Closing Thoughts

- Past work was driven by stakeholders. Industry on the pharmacy side has moved forward on SCRIPT.
- It would be helpful for all payers to understand that the standard is allowed under HIPAA.
- Commercial payers use the formulary and benefit standard that exists today
- The vision was that this information could be automatically extracted out of the EHRs and included in the PA request

Margaret Weiker, Director of Standards Development, National Council For Prescription Drug Programs

Margaret Weiker shared details of NCPDP.

- NCPDP is a not-for-profit, American National Standards Institute (ANSI)-accredited, Standards Development Organization (SDO) with over 1,600 members representing virtually every sector of the pharmacy services industry.

- NCPDP is a member-driven organization. Our diverse membership provides leadership and healthcare business solutions through education and standards, created using the consensus-building process.
- Best Practices for Patient Safety
- Safe Use of Acetaminophen, mL Dosing
- Real-time Prescriber and Pharmacy Data Products

Electronic Prior Authorization Process for the Pharmacy Benefit using SCRIPT Standard

- More than 50% of all pharmacy electronic prior authorizations are not sent electronically. The process is manual which leads to 37% of prescriptions being abandoned
- The process can be automated and can be done prospectively or respectively, as was discussed earlier
  - Prospectively, the patient gets the drugs 13.2 days sooner
- There is a telecommunication standard, but most payers don't support.

Electronic Prior Authorization (ePA) Transactions in SCRIPT Standard

- Supports an electronic version of today's PA process (i.e., PBM/payer provides prescriber with a set of questions they must answer for PA consideration) covered by pharmacy benefit
- Provides a standard structure for exchanging the PA questions and answers between prescriber and payers, while allowing for payers to customize the wording of the questions
- Additionally, supports elements that allow for automation of the collection of data required for PA consideration (i.e., coded references for each question (e.g., LOINC, SNOMED, CDA template) allowing an EHR vendor to systemically pull data from patient's medical record)
- Supports both a solicited and unsolicited model
- Reuse of SCRIPT functions, elements, exchanges
  - Definitions for common elements: Header, Patient, Prescriber, Pharmacy, Medication Prescribed, Benefits Coordination
  - Attachments
  - Acknowledgment transactions: Status, Verify, and Error

ePA Transactions in SCRIPT Standard

- PA Initiation Request/Response (used in the solicited model only)
  - Prescriber requests the information required to accompany a PARequest for a particular patient and medication.
  - PBM/payer responds with the information required to accompany a PARequest or an indication a PA isn't required for the patient and medication.
  - Response may be sent to the prescriber to renew an existing PA.
- PARequest/Response
  - Prescriber sends the information requested in the PA Initiation Response (solicited model) or information agreed upon outside of the PA transactions by the trading partners (unsolicited model).
  - PBM/payer responds with PA determination status (e.g., approved, denied, pended, more info required) and details specific to the status.
  - Repeat request/response transactions when more info required.
- PA Appeal Request/Response

  - Prescriber requests the information required for an appeal and used to submit the appeal information for a prior authorization determination.
  - PBM/payer responds with the information required to accompany an appeal or indicates the outcome of an appeal.
- PA Cancel Request/Response
  - Prescriber requests a PA Request that's in process be canceled.
  - PBM/payer responds with a cancellation status.

Electronic Prior Authorization History

- NCPDP SCRIPT 2013 Published
  - Standard includes ePA transactions
  - Educational sessions
  - Implementations begin/continue
- In 2014 NCVHS did recommend the 2013101 version be adopted and that has not been done
- Today the SCRIPT standard version 2017071 should be adopted to streamline and standardize

Recommendations

- Adopt under HIPAA the NCPDP SCRIPT Standard Version 2017071 Prior Authorization transactions only, for the exchange of prior authorization information between prescribers and processors for the pharmacy benefit
- EHR vendors must incorporate Prior Authorization transactions into their software and be integrated into the prescriber's workflow
- Health Plans/Processors/PBMs must evaluate the requirements for a prior authorization, incorporate analytics into the decision process, publish requirements and support ePAs
- NCPDP must complete enhancements to the Formulary and Benefit Standard and development of the Real-Time Pharmacy Benefit Standard

NON-MEDICATION WORKFLOW (DURABLE MEDICAL EQUIPMENT, REFERRALS, IMAGING, PROCEDURES)

John Kelly, Principal Business Advisor, Edifecs, Chair, Work Group for Electronic Data Interchange (WEDI) Prior Authorization Council

John Kelly shared that HIPAA requires the Secretary of the Department of Health and Human Services (HHS) to adopt standards for health care transactions to enable electronic exchange of health information.

- WEDI was named by the Secretary of HHS in HIPAA legislation as an advisor to HHS, and continues to fill that role
- Broad industry providers across public and private sectors. Deep subject matter expertise. Hoping to help HITAC members to inform policies.

Who is the WEDI Prior Authorization Council (PAC)?

- Goal is to build a cross stakeholder view of PA
- Hoping to reduce the administration burden of the PA process

PAC Findings

- No directive effort to reduce the burden on providers for PA
- 14.9 hours per week per physician is spent
- 1 million practicing physicians in the US
- $33/hr average national hourly wage for healthcare workers
- Cost of PA is ~$25 billion

Burden Reduction

- The burden can be reduced by reducing physician office cost.
- Suggest single action order entry
    - Once a provider puts an order for service into the EHR and record as part of the normal workflow, machines should be able to handle the rest
- If invest in an automated model will reduce costs and implement a more robust system of delivering care

Single Order Entry

- Machine based workflow to fulfill PA requirement
- There is a white paper that was distributed that contains more details
- Create an opportunity to lower costs and improve quality

Government Accountability Office (GAO) Report

- GAO released a report that concluded CMS should take actions to continue prior authorization efforts to reduce spending in Medicare
- Pressure is needed to make research development commitments to bring out single action order entry.

John Kelly noted that this is a complex process and business process redesign is necessary. Instead of a standard way, there needs to be collaboration across stakeholders.

- Pursue harmony between x12 NCPCP HL7 FHIR
- Minimize capital burden and service disruption to maximize breadth of adoption
- Build a common glide path to a best practice approach

Current Activities

- Leadership in the form of Carrots and Sticks is required for all stakeholders
- DaVinci PA
- HIPAA PA
- CAQH PA
- NCPDP PA
- Proprietary Solutions

John Kelly thanked the HITAC for the opportunity to present.

Robert Dieterle, Enablecare, CEO, Program Management Office HL7 Davinci Project

Robert Dieterle noted it is hard to get real-time information to support PA.

- Only 12% of PA transactions are automated end-to-end.
- Focused on trying to enable using FHIR to reach into the providers EHR to extract information to support the PA transaction
- On the payer end to the extent establishing FHIR based clinical decision support technologies to send information back

Da Vinci Overview

- HL7 supported project established about a year ago
- Multi-stakeholder environment
- Creating pilot projects to prove standards work
- Approximately 30 members
- Four of the largest EHR vendors
- Over 12 provider organizations
- Shifting from fee for service to value-based care, this is where Da Vinci efforts are focus
- Aligning requirements for a use case
- Reference implementation to exercise implementation guide
- Simulating provider and payer interaction
- Test suites to validate compliance
- Two use cases going through balloting process
- Coverage Requirements Discovery
- Providers send CDS Hooks based request, with appropriate clinical context to the responsible payer
- Use CDS Hooks to initiate transactions
- Use the ability to trigger in clinical workflow initiate conversation with payer
- Coverage requirements discovery to allow for planning

Using CDS Hooks initiate an action to the payer and evaluate what is being ordered and decided whether there is a need for prior authorization. Pull information automatically from the clinical record. More information needed could use structured data capture to ask for additional information.

Two other approaches

1. Payer effort use CDS Hooks that have the payer check the record to support PA and do nothing but issue the PA number (or whatever the next step might be)
2. Look at doing this on the provider side
    a. Have all the rules necessary to evaluate the information on the provider side. If all requirements met, issue the PA and do within provider workflow.

CDS HOOKS

Ken Kawamoto, HL7 CDS Hooks: Overview and Potential Application For PA, Price Transparency, And Disease Management

Ken Kawamoto reviewed HL7 Clinical Decision Support Hooks.

HL7 CDS Hooks

- CDS Hooks is vendor agnostic remote decision support specification
- This is a technology that can be used across use cases
- Trigger point
    - The only hook that is being adopted is patient view (when the patient chart is open)
- Data supported in FHIR in an EHR can be pulled for use
- In 2019, release a 1.0 specification with patient-view hook (now)
- Price transparency could be used the same way as prescribing

Needs

- Expansion of EHR FHIR support for needed data (e.g., detailed smoking history)
- Expansion of specified and supported hooks (esp. for ordering), not currently supported in vendor products
- Regulatory guidance from HIPAA perspective (also needed for FHIR and SMART)
- Standard EHR trigger guard specifications
- Greater support for asking users questions and enabling order placement
- Application to important use cases
    - Prior authorization is an important use case

Public and Private Payer Perspective

Kate Berry, America's Health Insurance Plans (AHIP)

Kate Berry explained AHIP's role. AHIP is the national association whose members provide coverage and health-related services that improve and protect the health and financial security of consumers, families, businesses, communities and the nation.

Prior Authorization

- 30% of healthcare services are potentially unnecessary and harmful
- PA is a tool used for safety

Prior Authorization Policies

- Developed using evidence-based criteria, input from clinicians (e.g., P&T committees)
- Reviewed and revised at least annually
- Accessible to participating providers, members
- Exceptions processes
- Many aspects of UM - including use of evidence-based criteria, input from clinicians, exceptions, timeframes, annual review/revision – part of accreditation

Potential to Improve the Process

- ePA has potential to streamline process for all stakeholders
- Goals of AHIP's ePA pilot project:

- o Multiple approaches (e.g., clinical domains, clinical settings)
- Standards-based, scalable solutions
- o Payer agnostic
- o Integrated with practice workflow

Process and Next Steps

- Sent request for proposals (RFP) to vendors
- Finalists presented to AHIP members
- Now scoping projects with 2 vendors
- Will engage independent organization to evaluate impact
- The demonstration is expected to be relatively short term
  - There will be an independent evaluator to understand the impact of the payer, patient, and provider
- Targeting to complete evaluation and release report (late 2019/early 2020)

Closing

- There isn't a perfect solution, but there is a lot of potential for automation to reduce the phone calls and faxes between provider offices and insurers
- There is great potential, but no one vendor can solve the entire problem
- Build on what is available and make progress
- Brought in top vendors and have selected a couple of vendors to scope the details of the demonstration project
  - This is a collaborative and detailed process
- Working with America's Physician Groups on a continuum of value-based care and all of the functions that need to be performed as part of risk-based population health
  - How to share responsibility in performance-based contracts?

Robert Wah asked for more information about Gold Carding.

Kate Berry noted that this is an opportunity for those who perform well. Different physicians perform differently on different types of services. If it is known that there is an oversight, more effort might be put into documentation when a provider is gold carded, the performance changes. There are state laws that restrict the ability for different enrollees to be treated differently. There are a lot of concerns about this. Plans are doing this, especially in risk-based arrangements. Electronic prior authorization has a greater potential for improving the process.

Melanie Combs-Dyer Director, Provider Compliance Group, Center for Program Integrity, CMS

Melanie Comb-Dyer commented that provider authorization is broken, but is an important tool to ensure compliance. The PA process needs to be fixed.

Medicare FFS Definition of Prior Authorization (PA)

- Prior authorization (PA) does not create new clinical documentation requirements

- It requires the same information that is already required to support Medicare payment, just earlier in the process.
- PA allows providers and suppliers to address issues with claims prior to rendering services and submitting claims for payment, which has the potential to reduce appeals for claims that may otherwise be denied.
- Medicare FFS believes using a PA process will help ensure that all relevant coverage, coding, and payment requirements are met before the service is rendered to the beneficiary and before the claim is submitted.

Providers and Prior Authorization

- Medicare FFS is listening
  - Providers have said it is too difficult to figure out when PA is required.
  - As part of provider listening sessions, CMS and ONC have heard repeated suggestions that payer should:
    - Publicly disclose, in a searchable electronic format, a payer's requirements (including prior authorization requirements) for coverage of medical services.
- Once the provider knows PA is required, the associated requirements and processes are burdensome and difficult to complete.
  - Lack of standardization and effective technology solutions to automate these processes.
  - Not only difficult for the rendering provider, it is especially difficult for ordering provider. Some payers require providers to fill out PA forms.
- Medicare FFS would like to leverage data already present in the EHR to reduce re-documentation in the clinical note.

New Da Vinci Standards to Help Reduce Provider Burden

- New FHIR Standards that Medicare FFS is using to create a Documentation Requirement Lookup Service (DRLS)
- New FHIR Standard for Attachments
- New FHIR Standard for PA Requests

Medicare FFS Documentation Requirement Lookup Service (DRLS)

- DRLS will allow providers to discover prior authorization and documentation requirements at the time of service in their electronic health record (EHR) or integrated practice management system through electronic data exchange with a payer system DRLS Goals:
- Heard from providers that documentation requirements are too hard to find
- CDS Hooks will be used as a trigger

New FHIR Standard for Attachments

- Medicare FFS is closely monitoring the HL7 workgroup creating the Clinical Data Exchange (CDex) Standard.
- Attachments are important
  - Volume of Medical Record Review
- Electronic Submission of Medical Documentation (esMD)
  - Currently uses the CONNECT Standard

- In Calendar Year 2017 the total Program Payments for Medicare Parts A and B was $337.0 billion
- Medicare Medical Review Contractors typically only conduct medical review on less than 1% of claims
- The Electronic Submission of Medical Documentation (esMD) system enables providers to send medical documentation to review contractors electronically.
    - The system is Exchange compatible, based on standards developed by the Office of the National Coordinator (ONC) for Health Information Technology.
    - Most recently, the esMD initiative has developed the capability to send requests electronically and also receive medical records generated according to common standards for EHRs.
    - Allowing health care providers to submit requested records directly from their own systems promises to further reduce burden.

New FHIR Standard for PA Requests

- Medicare FFS will be closely monitoring the HL7 workgroup creating the Prior-Authorization Support Standard.
- NCVHS has recommended that HHS should promote and facilitate voluntary testing and use of new standards.
- A good example of a new standard to test for HIPAA would be the HL7 FHIR standard, currently in pilot for various use cases, including prior authorization with various public-private sector organizations, including the CMS.

Sagran Moodley, Senior Vice President, Clinical Data Services, United Healthcare, Chair Steering Committee Davinci Project, Co-Chair Documentation Requirement Lookup Service

Sagran Moodley shared that the compass is the triple aim: improve patient experience, improve health outcomes, and reducing health costs is critical. The administrative burden is shared across all stakeholders and can delay care.

Prior authorization is not consistently adopted. The narrative has changed and evolved.

DaVinci Project

- The project supports and promotes the adoption of standards while driving down administrative burden.
- Imagining a world where the rules need to be shared in real time, as the population evolves
- Health plan agnostic and available at the point of care. Open the opportunity to think about other things. Gold carding at the procedure, provider, and patient level.

Sagran Moodley emphasized that need to get to the site of service and site of care cost transparency. Cost transparency for consumers is important. There is a need to force all payers to expose rules.

Discussion

Robert Wah opened up for discussion.

Arien Malec commented that there are ecosystem issues related to the availability of formulary limitations. The complexity of adjudication is reflected in things that can be automated. This is a classic ecosystem problem. There is good technology with CDS Hooks and FHIR to take away the complexity. Intermediaries may not be adjudicating the rules. Between the payer and standards panel, there might be an opportunity to get at some of the ecosystem dependencies.

- **Kate Berry** commented that automating prior authorization needs to be done piece by piece, and there are no easy answers. All players need to work together on multiple paths.

Aaron Miri questioned how prescription drug monitoring programs (PDMP) plays a role and how HITAC can help with this process?

- There are issues with PDMP. Usability and interoperability across states are an important tool to address prescribing of opioids and other controlled substances.
- **Margaret Weiker** commented that NCPDP has a standards-based facilitator role based on the SCRIPT standard. This can do the PDMP check and feeds into the telecommunication standard which is the claims standard.
- **Ken Kawamoto** commented that ONC has relevant efforts:
  - Defining ways to use FHIR to pull PDMP directly
  - When is it necessary to check the PDMP? CDS based CDC guidelines
  - Currently no guide for PDMP and no other prescribed medication.
- **Donald Rucker** noted that PDMP is a bit of a different process; unfortunately, today's discussion won't solve these issues.

Leslie Lenert commented that this process needs to work for patients. The pilots need to provide patients with the information they need, and the system needs to be responsive to patients. There should be one comprehensive summary statement of the electronic medical record that is transmitted for PA purposes. He suggested using machine learning methods, require that the adjudication be done based on the C-CDA and then does it within seconds of computation. He suggested the creation of a standard document, using the best technology to do this rapidly. There needs to be a limit on the time of computation.

- **Melanie Comb-Dyer** commented that her pilot is reaching out to the CARIN alliance and others that can be a part of the pilot from a patient perspective.
- **Unknown** if the information is structured, we should be able to come up with a method. A machine could assemble an array of data and pass to the other machine trying to make a decision. He believes that this is where this ends up.

Sheryl Turney thanked everyone for their presentations. She noted that this is not an easy problem to solve and she is interested in Leslie Lenert's suggestion. She agrees that the patient can't be forgotten in all of this and is an issue that needs to be solved. There is not overwhelming support when doing provider contracting to share clinical data. This will need to be a collaborative effort that everyone needs to participate in, and she wants to help the payer community lead that change.

Steven Lane commented that there have been other use cases where special circumstance documents have been created. The approach noted by Leslie Lenert is intriguing and could create a custom created PA documentation type.

Cynthia Fisher commended Leslie Lenert's idea. Most of this process is built upon payment. She suggested flipping this to look at the patient's experience along with the physician interaction to determine the care path forward. Thinking further about real-time decision support impacts the patient and their financial health.

Andy Truscott noted that there are standards available. The implication of what Leslie Lenert is suggesting is a shift of onus where the patient is no longer asking for permission. It is a fundamental shift that is needed to alter the process.

Leslie Lenert noted that as the patient, he could check different places using an interface that allows him to review pricing by managing his own care (via Apple HealthKit, for example).

Bill Stead summarized what he heard throughout today's discussion. There are two issues: 1) Need to resolve this problem without manual intervention; 2) Patients need to be provided care when it is needed. In the current environment, there is the possibility of narrowing administrative processes to get additional information that is needed. There is an embarrassment of riches in the number of potential solutions that are underway. Now there is a need to step back and figure out how to become agile and thoughtfully plan alternative paths. He also heard there is a need to have an element of a revolution that would fix some of the current practices which are analogous to information blocking. Key players need to come together to strategize and help the clinician know what to recommend, and the patient knows what to accept.

Thomas Mason thanked the presenters for their time and participation. He thanked the HITAC members for sparking the stimulating discussion to identify solutions to prior authorization. He thanked Bill Stead and NCVHS for their participation.

Andy Gettinger thanked everyone and apologized for squeezing too much into the timeframe. This started with clinician burden, and the work that is going to be done will have a huge impact on clinicians downstream.

Robert Wah thanked all of the panelists and noted his appreciation for the work that everyone is doing. He is looking forward to using technology and policy levers for improvement.

Lauren Richie opened the lines for public comment.

Public Comment

Comments received in person

Shelly Spiro, Pharmacy HIT Collaborative, the vision is to ensure the infrastructure will better enable pharmacists to help optimize person-centered care. The mission is to advance and support the usability and interoperability of health IT by pharmacists to help optimize person-centered care. Over the last nine years, the Collaborative dedicated efforts to promote the use of standards within clinical documentation systems used by pharmacists. The collaborative supports the efforts of NCPDP electronic prior authorization standards, within the electronic prescribing standard SCRIPT. The collaborative supports

the DaVinci project's prior authorization case and supports the efforts to ensure pharmacists writing clinical services are included in any electronic prior authorization process for medications devices and services.

Comments in the public chat during the meeting

Shelly Spiro: I should be in the queue to make a public comment.

Shelly Spiro: Please let me know if I'm not in the queue.

Wrap Up and Next Steps

The committee will revisit the topic of prior authorization at a future meeting. The next HITAC meeting is in-person on April 10, 2019.

Adjourn

Lauren Richie adjourned the meeting at 1:00 p.m. ET